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A Clinical Study on Itrifal Shahatra and Sharbat Unnab to Evaluate the Mechanisms of Action and Unani Principles in Buthūr (Acne)

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Abstract

The current study assesses the possible mechanisms of action of Itrifal shahatra and sharbat unnab in Buthūr (Acne) with the support of Unani principles and evidence of the trial. The skin eruptions like macules, papules, and pustules are described in the Unani classical literature as Buthūr. The main cause of Buthūr is khilt e Raddi (Morbid Humour) due to the derangement of Akhlat (body humor). Musaffi-e-khoon (Blood purifier), Muhallil-e-auram (anti-inflammatory), Dāfi‘-i-Ta‘affun (anti-septic/antibiotic), and Moaddilat-e-dam (alterative) are used in Unani System of Medicine for the management of Buthūr. Several clinical studies support this trial. There is a need to develop different therapeutic options for the treatment of Buthūr-e-Jild with possible mechanisms of action according to Unani principles. An open-level study was conducted in RRIUM, Patna, Bihar for 2 years. 128 subjects were randomly selected; among them, 100 cases completed the course of study. All the subjects were given Sharbat e Unnab 20 ml and Itrifal Shahatra 5 grams twice a day for three weeks. The stages of progress was recorded in the expression of percentage efficacy as calculated from enhancement in the signs and symptoms in the visual analog scale. The results were statistically analyzed and it showed that the Unani Pharmacopoeial formulations Sharbat-e-Unnab and Itrifal shahtra were significantly effective in the management of Buthūr and possible mechanisms of action are also evaluated.

Keywords: Buthūr, Sharbat Unnab, Itrifal Shahatra, Acne, Unani Medicine

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INTRODUCTION

Furuncle/Boils are described by the name of *Buthūr-e-jild*in the ancient classical Unani literature. These are skin diseases characterized by inflammation of hair follicles and the appearance of rashes including small red papules, vesicles, or pustules. Sometimes pustules/boils spread all over the body due to excessive causative substances (*Kasrat-e-Maddah*). Pustules/Boils are very common in the Indian population and affect 80–90% of young adults.

The Buthūr are commonly found on the face, neck, armpit, buttocks, and thighs and are classified according to the predominance of Khilt (Humour). The Usool e Ilaj (principle of treatment) is Moaddilat al Dam, Musaffiyat al Dam, and Muhallil advia. This Usool e ilaj is being practiced since incipient by Unani scholars [1, 2, 3].

MATERIAL AND METHODS

This is an open-level validation study conducted in OPD/IPD of RRIUM, Patna, Bihar, after the approval of the institutional ethical committee. 128 subjects were randomly selected amongst the patients provisionally diagnosed to be suffering from *Busur*, after fulfilling all the inclusive and exclusive criteria, among them 100 cases completed the study. All the cases were subjected to biochemical and pathological investigations like CBC, LFT, KFT, etc. before and after the trial. The pharmacopoeial formulation *Itrifal Shahtara* 5 gram and *Sharbat Unnab* 20 ml were given twice a day after a meal with water for three weeks. *Itrifal Shahtara* having six single drugs viz. shahtara, post e halelazard, post e halelakabuli, sanamakki, gul e surkh and maweez munaqqa and Sharbat Unnab having unnab, qandsafaid and normal water 5.The total duration of treatment was 3 weeks and the duration of the research project was two years. The patient was assessed clinically on the baseline, 7th day, and end of the treatment (21st day). The subjective and objective observations were recorded in the follow-up sheet. Concomitant therapy was not allowed throughout the study. The Unani principles were evaluated with the help of Unani classical literature such as Kitab al Fakhir, Dastoor, Moalejat-e-Nafees, Maraz-ul-Bahrain, Al-Qanoon-Fi-Al-Tib, Qanuncha Ma'a Risala Qibriya, Maojiz, Ghina Muna, Takmil Al Bahrain, Tazkirat-ulul-Albab wa Al-Jame Lil Ajab-il-Ajaib, Iksire Azam and Mazahirul Ilaaj. In addition, an extensive search through scientific databases including Pubmed, Science Direct, and Google Scholars was searched. The following terms were applied to the literature search Buthūr, Sharbat Unnab, Itrifal Shahatra, Acne, Unani principles and mechanisms of action performed to find the Unani and modern description of this condition.

RESULTS AND DISCUSSION

Pharmacopoeial formulations *Itrifal Shahtara* and *Sharbat Unnab* were used to treat *Buthūr-e-jild*in this study 41 (41%) males and 59 (59%) females were registered which indicates more prevalence of the disease among females. The highest number of patients treated was from *safravi mijaz* (bilious temperament).

All the investigations were done at the baseline and after completion of the study i.e., CBC, Hb%, TLC, DLC, ESR, and LFT (Serum Bilirubin, SGOT, and SGPT, Serum Alkaline Phosphates) and KFT (Urea and Creatinine) to assess the safety of the drugs were found within the normal range and there was no significant difference in any of the above parameter readings after the use of the drugs.

The trial showed that pharmacopoeial formulations *Itrifal Shahtara* and *Sharbat Unnab* had a significant beneficial effect on the symptoms of *Buthūr-e-jild*that was erythema, itching, and pain with Vesicles/Pustules/Macules/Papules

The test drugs Itrifal Shahatra have Musaffi-e-Khoon (Blood purifier), Dafeye-e-Fasade-khoon (regulate the hemodynamic disorders) Dafaye-e-Taaffun (Antiseptic), Maneywa Dafeye Tadiya (Bacterio static and Bacteriocidai), Qatil-e-Kirm-e-Shikam (Anti-helminthes). Nafaye Kharish (effective in eczema/lichen), Mudir e Baul properties as per old Unani treatise. Another test drug Sharbat-e-Unnab had moaddil-e-dam, musaffi-e-khoon, anti-oxidant, and munaffish-e-balgham properties. All the above-mentioned pharmacological properties are the part of usool e ilaaj of *Buthūr-e-jild*that's why test drug showed highly significant in *Buthūr-e-jild.*

Figure 1, shows that test drugs were significantly effective and improved the disease conditions such as pruritus, vesicles, pustules, papules, pain in the lesions, generalized pain, and marked reduction of no of lesions. The p-value was ($p<0.05$).

Figure 2, shows the efficacy of the drugs on the main complaints of the patient, i.e. vesicles, pustules, pruritus, macule, and papules with or without the association of erythema, itching, and pain. The effect of the Unani formulation was found to be effective in relieving the symptoms on type of lesions i.e. on vesicles, 77.61% in erythema, 81.97% in itching, and 77.4% in pain, on pustules, 53.44% in erythema, 59.24% in itching and 81.06% in pain and on pruritus, 55.34 in erythema, 60.00% in itching and 77.40% in pain respectively at the end of the 3rd week there was a subjective improvement in the symptoms. The overall effectiveness of formulation to relieve the number of lesions was 51.27%, and on macules, 65% in erythema, 74.21% in itching, 91.18% in pain and on papules, 64.06% in erythema, 73.96% in itching and 85.15% in pain respectively.

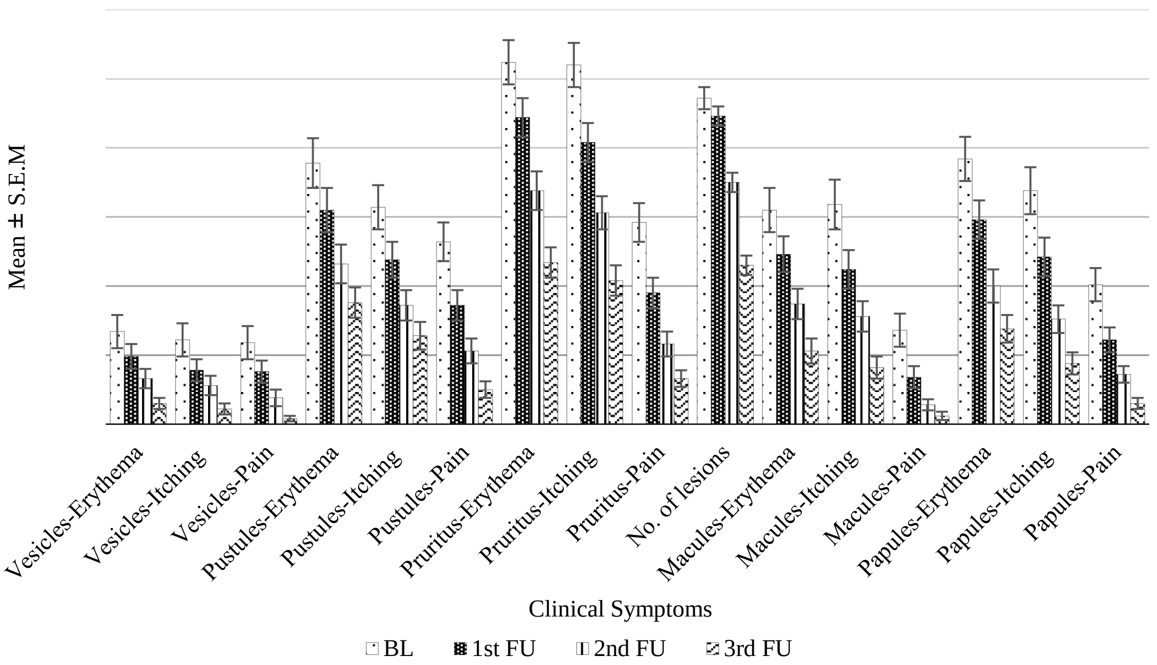

Figure 1. Effect of drugs on clinical parameters.

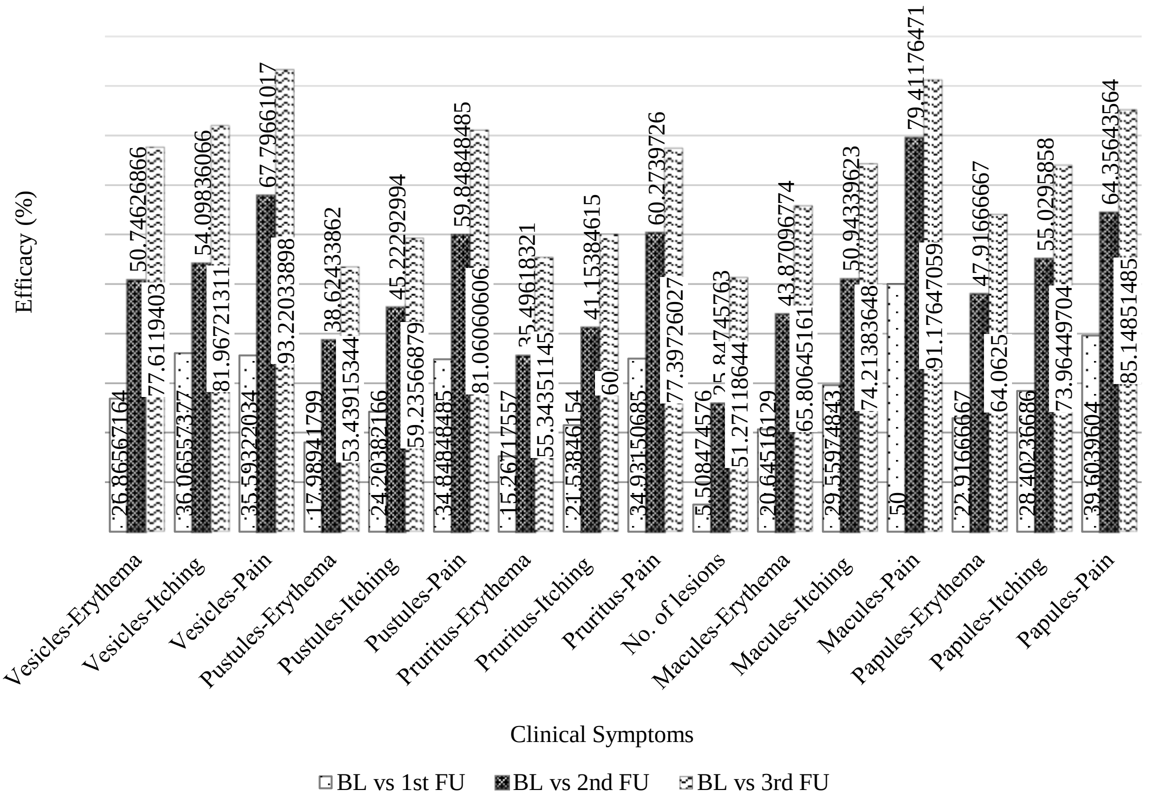

Figure 2. Efficacy (%) drugs on clinical parameters.

The important drugs in the formulation which directly affect the signs and symptoms are Shahatra (Fumaria officinalis), Post HalilaZard (*Teminalia chebula),* Post Balela (*Teminalia chebula),* Sena (Cassia senna), Gule surkh*(Rosa damascene)*, Maweez Munaqqa *(Vitis vinifera)* and Unnab (Ziziphus jujuba). The cumulative effect of Itrifal shahatra has Musaffi-i-Khoon (Blood purifier), Dafeye-i-Fasade-khoon (regulate the hemodynamic disorders) Dafaye-i-Taaffun (Antiseptic), Maneywa Dafeye Tadiya (Bacterio static and Bacteriocidai), Qatil-e-Kirm-e-Shikam(Anti-helminths). Nafaye Kharish (effective in eczema/lichen simplex chronicus), Mudir e Baul properties [4, 5] as per old Unani treatise. Another test drug Sharbat-e-Unnab has moaddil-e-dam, musaffi-e-khoon, anti- the part of usool e ilaaj of *Buthūr-e-jild*that's why test drug showed highly significant in *Buthūr-e-jild.* oxidant and munaffish-e-balgham properties [5]. All the above-mentioned pharmacological properties are possible mechanisms of action of Unani formulation comparing both Unani as well as Allopathic principles.

The formulation contains eight single herbs having the following properties described one by one. Sharbat-e-Unnabcontin only one ingredient i.e. Unnab (Ziziphus jujube) acts asMoaddil-i-Dam (Alterative), Musaffi-i-khoon (Blood purifier), Munaffis-i-Balgham (Expectorant), Nafe-laza-i-Meda (Effective in gastric erosion), Mane-Jiryan-u-ddam (Anti-coagulant), Chechak mai mufeed hai (Anti-viral), Munzij-e-akhlat-e-Ghaliza (concoctive of viscid humour), Mushilakhlat-e-Raqeeqa, Nafe-khasunat Halq (effective in pharyngitis), Nafewaja-al-Kulliyawa Jigar (hepato and renal protective) Nafe Amraz-e-Maqad wa suzish-e-Masana, Nafewa Mujarrab Sual e Yabiswa Khasunat Halq (useful in dry cough and pharyngitis), Nafe Zeequnnafas, Nafe Bathurwa Garmi Dana, Muzayyad Aklat Swalha, Nafe Quruh Ama, Nafe Khujli (renal protective), Post Mudammil e Quruh (wound healer), Mulayyan (laxative) [6, 7] in Unani classical literature as well in modern scientific studies also reveal these properties. A lot of studies have shown that the Unnab (jujube) fruit contains several bioactive compounds, including triterpenic acids, flavonoids, cerebrosides, phenolicacids, α-tocopherol, β-carotene,and polysaccharides[8, 9].

Triterpenic acids are in the type of free acids or glycones such as saponins, which have multiple biological effects including anti-inflammatory [10], antimicrobial [11], hepatoprotective [12], and antioxidant [13] properties.

The prepared different polarity leaves and fruit extracts were used to determine their antioxidant activity by modified free radical scavenging method [14]. Anti-carcinogenic and antitumor activities of triterpenic acids are also present [15]. According to Guo et al. in 2009 identified 10 triterpenic acids are found in jujube fruit [16]. It also has an anti-inflammatory and antispasmodic effect [17] and strong anti-allergic activity [18].

Shahatra (Fumaria officinalis) is one of the ingredients of Itrifal Shahatra acts as Muqawwi-i-Jigar (hepatotonic), Muqawwi-i-Mi'da (stomachic), Mufattih-i-Sudad-i-Jigar waTihal (deobstruent of Liver and Spleen), Mukhrij-i-Safra (Bile expulsive), Mukhrij-i-Sauda (Black bile expulsive), Musaffi-i-Dam (Blood purifier), Musakkin-i-Alam (Analgesic), Dafi'-i-Humma (antipyretic), Mane-Qay (Anti-emetic), Mudirr-i-Bawl (Diuretic), Mushtahi (Appetizer), Nafe Tap-e-Kohna (antipyretic), NafeJarb (anti-scabies), Nafe Dad waHikka (anti-dermatophytes), Mulayyin (Laxative), Maneywa Dafeye Tadiya (Bacterio static and Bacteriocidai), Mudirr-e-Bawl (diuretic)[6;7] properties mentioned in Unani classical literature with the evidence of modern researches.

Pharmacological actions of Shahatra (Fumaria indica) are Hepatoprotective activity [19] Smooth muscle relaxant activity, spasmogenic and spasmolytic effect, antibacterial activity, antifungal ctivity [20] anti-inflammatory and anti-nociceptive activity, anti-oxidant activity [21] mentioned. Other drugs in the formulation are Psot Halila-e-Zard, Post Halila-e-Qabli and Post Halila-e-Siyah (Terminelia chebula) all are different forms of Terminalia chebula fruits. Pharmacological actions are mentioned in classical Unani literature as well as in modern studies are Halila Siyah: Munzij wa

Mushil Sauda (Melancholic concoctive and purgative), Muqavvi Dimagh (Brain tonic), Muqavvi Qalb (Cardiac tonic), Nafe Bukhar Muzmin (Anti pyrexia), Rang ko saafkartahai, Nafewaja-al-Tilli (Spleenache) Muqavvi Hawas (Sense enhancer), Muqawwi-e-Ahsha (Visceral tonic), Musaffikhoon (Blood purifier), Nafewaja-al-Tilli (Spleenache), Mushil (purgative), MushilSauda (Melancholic purgative), Muqavvi Meda (An agent with strengthens the stomach and improves its function), Muqavvi Asab (Nervine tonic), Muqawwi Hafzawa Dimagh (Brain tonic).

Halila Zard: Munzijwa Mushil Safra (Bile concoctive and purgative), Awaz ko saaf karti hai (Hoarseness of voice), Dafe Alam (Analgesic). Muqavvi Meda (Gastric tonic), Muqawwi-e-Dimagh (Brian tonic), Muqavvi Zehan (Memory enhancer), Muqavvi Hawas (Sense enhancer), Mufatteh Sudud (deobtuctent), Nafe Khafqan (Palpition), Janoon (Psychiatric disorders), Mujaffi-i-Ratubat (Desiccant), Nafe Bawasee (Ati-haemorrhoid), Mushil-i-Safra (bile purgative), Muqavvi Meda (gastric tonic), Nafe Isterkha Meda (Gastroparesis), Nafe Bawaseer (effective in haemorrhoid), Muqawwi Qalb (Cardiac tonic), Muzmin Aza shikni (muscle relaxant), Suda (Headach), Rang ko saf karta hai (improve complexion of skin), Budhapa Waqt se Pahle nahi aanedeta (Delay aging).

Halial Qabli: MushilSauda (Melancholic purgative), Muqawwi Qalb (Cariac tonic), Mushil Akhlat-e-Thalasa (purgative of three humours), Muqawwi Qalb (Cariac tonic), Malankholia (Melancholic), Nafe Sara (epilepsy) [6, 7], safe and effective purgative, astringent and alterative, stomach-ache, laxative, and tonic, removing the bile and phlegm and to adjust bile [22].

Terminelia chebula contains tannic acid 32% contain: Purgative principle of anthraquinone and sennoidnatic is also present. Total eight compounds viz. Isolation and checked out of reverse phase chromatography of *Terminalia chebula* were gallic acid, chebulagic acid, and penta-O galloyl-β-D-glucose [23].

Terminalia chebula has been noted to possess potent antioxidant properties due to the presence of phenolic compounds present in its extract [24]. *Extract of Terminalia chebula* and *Terminalia chebula* is much effective against Helicobacter pylori and Anti-fungal activity [25], this is also effective in Anti-amoebic and immune-modulatory activities, Anti-helminths activity, Anti-viral activity [26], Anti-diabetic activity, Anti-ulcerogenic activity and Cardio-protective activity of *Terminalia chebula* [27].

Gule surkh (Rosa damascena Mill) is one of the ingredient of Itrifal Shahtra, its pharmacological actions according to Unani classical literature as well as modern research are Muqawwi Qalbwa Dimagh (Cardiac and brain tonic), Nafesuda (Headache), Mshil (Purgative) fresh flower but Qabiz (Astringent) dry flower, Nafesuda (Headache), Nafe Tip (Anti-pyretic). Muqawwi Qalb (Cardiac and tonic), Muqawwi Arwah, Mufarrah (exhilarant and mood elevator), Lateef mushily (Gentle emollient), Muhallih (anti-inflammatory), Nafe Dard Kulliya (Renal cholic), Musakkin safra wa Balgham (neutralized the heat of phlegm and bile), Muqawwi Aza (tonic), MuqawwiMedawa Jigar (gastric and liver tonic), Mufatteh Sudud-e-Jigar (deobstruent of the liver), Muqawwi Ruhwa Qalb (cardiac tonic), Nafe Khafqan Wa Gashi (effective in palpitation and syncope), Muqawwi Meda (gastric tonic), Nafe Quruh-e-Ama(effective in gastric ulcer) [6, 7].

The following compounds are found in *Rosa damascena Mill* as citronellol, geraniol, nerol, phenyl ethyl alcohol, nonadecane, nonadecene, eicosane, heneicosane, tricosane, a-guaiene, geranyl acetate, and eugenol have been reported in different geographical areas [28]. The actions of Rose are mildly stringent, aperients, carminative and refrigerant, and cardiac tonic

As compared to Unani as well as modern research has proved that Rosa damascena acts as anti-viral properties, antibacterial properties, antioxidant activity, analgesic and anti-inflammatory activities [29].

Some studies reveal the anti-carcinogenic, cytotoxic effects, and anti-tumor properties of R. damascena. Relaxant and anti-depressant activity of R. Damascena via stimulating the b-adrenergic receptors [30].

Senna (Cassia angustifolia) is also an ingredient of Itrifal Shahatra and its pharmacological actions are Mushil akhlat salasa (purgative of three humours), Musaffi khoon (Blood purifier), Qatil-e-kirm e shikam (Anthelmintic), Nafewaja-al-mafasil (anti-arthritis), Nafe-Niqris (Gout), Nafe-Irqunnisa (Anti-sciatica), Nafesuda-e-shaqiqa (anti-migraine), Munaqqi Dimagh (Brain tonic), Muqavvi-e-Shar (Hair tonic), Nafe Sara (Anti-urticaria/anti-allergic), Nafe Kharishwa Bathur (effective in eczema and boils) [6, 7].

Purgative, but heavy dose causes intestinal irritation, nausea, tenesmus, intestinal colic, and abortion [31]. Senna leaves and pods contain anthraquinone glycosides which are dianthron derivatives of rehim, with two glycoside units i.e., Sennoside A and Sennoside B. These glycosides were first isolated by Stoll in 1941, believed to be the chief laxative principles of Senna [32]. Long-term use of Senna causes hepatotoxicity and gastrointestinal disorders due to excessive doses of anthraquinone present in the herbal extract of Senna [33].

The chief ingredient of Itrifal shahatra is Munaqqa (Vitis vinifera) and its pharmacological actions as per Unani and modern studies are MusakkinHararat-i-Safra (Febrile sedative of bile), Munaffis-i-Balgham (expectorant), Nafe-qurooh-e-Meda (anti-gastric ulcer), Muhallil (anti-inflammatory),Sartan, Gangarana, Bawaseer ke zakhm mai mufeed hai (wound healer/Gangerene), Muhallil Riyah (anti-flatulent), Mullayyan (laxative), Musammim Badan, Muqavvi Bah (Aphrodisiac), Muqavvi Medawa Ama (Gastrointestinal tonic). The actions of Senna leaves are laxative, nutritious, blood-purifier, demulcent, and expectorant. It showed broad-spectrum antimicrobial activity against Gram-positive and Gram-negative bacteria [34]. Resveratrol (3, 5, 40-trans-trihydroxystilbene) is a natural phytoalexin abundantly found in grapes and red wine, which has potent antioxidant [35], anticarcinogenic and antineoplastic [36], anti-aging as well as neuroprotective properties. It is also a potent anti-inflammatory and immunomodulator. Grape seed extract may have its potential application as a treatment for obesity. It inhibits the gastrointestinal digestion of lipids through the inhibition of lipase enzymes [37].

CONCLUSION

In this study, Itrifal Shahatra and Sharbat Unnab showed strong anti-bacterial, anti-fungal, anti-viral, anti-helminths, anti-amoebic, anti-ulcerogenic, cardioprotective, hepato-protective and modulator of humor as mentioned in classical Unani literature as well as modern scientific research both actions and mechanisms of action. Furthermore, research will help the better understanding of his mechanisms of action.

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